UNITED STATES ENVIRONMENTAL PROTECTION AGENCY ML44469

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Re: P-08-508 & 509

This letter concerns the Adsorption, Distribution, Metabolism, and Excretion Study (ADME, OPPTS 870.7485) conducted in rats and mice on the above referenced PMNs. This study was required under the Consent Order for P-08-508 & 509[1]. The first tier of the study was submitted by your company in December 2010. EPA has reviewed this study and finds it valid. The PMN test substance (P-08-509) is totally excreted by the rats and mice. The guideline calls for a consultation to determine whether a second tier, a repeated dose ADME study is necessary. As part of the consultation, EPA's technical and regulatory experts met with your company's technical experts and yourself on May 18, 2011. EPA then evaluated the results of the first tier and other relevant toxicity data, and considered the need for the second tier of the study.

EPA has determined that the second tier study is not necessary due to the results of the first tier, and that further pharmocokinetic data on this PMN substance will not further our understanding of the substances. This letter is to inform you that your company has fullfilled its obligations under the Consent Order for P08-508 & 509 for the ADME study, and that in accordance with the Testing section, paragraph (f), your company does not need to conduct the second tier repeated dose component of the ADME study.

If you have any questions or comments, please contact the program manager, Rose Allison at 202/564-8970.

Sincerely yours,

5011000291 6

Greg Schweer, chief
New Chemicals Management Branch

[1]Testing section page 5, Study 1) "Repeated dose metabolism & pharmocokinetics, rats

CONCURRENCES: New Chemicals Management Branch								
SYMBOL	7405	7403M	7405M	7405M				
SURNAME	Allison	Kiefer	Barkas	Schweer				
DATE	7/27/11	7-27-11	w/comment	8/1/11				

7/28/11

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